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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,491	02/28/2007	Shlomo Ben Haim	MET095,233410	9326
54942 7590 02/21/2008 WOLF, BLOCK, SHORR AND SOLIS-COHEN LLP 250 PARK AVENUE 10TH FLOOR NEW YORK, NY 10177				
EXAMINER MALAMUD, DEBORAH LESTLIE				
ART UNIT		PAPER NUMBER		
3766				
NOTIFICATION DATE		DELIVERY MODE		
02/21/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO@WOLFBLOCK.COM

Office Action Summary

Application No.

10/561,491

Applicant(s)

BEN HAIM ET AL.

Examiner

DEBORAH MALAMUD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 21-43, 74, 75 and 94-115 is/are pending in the application.
4a) Of the above claim(s) 1, 2, 74 and 75 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 21-31, 35-38 and 94-115 is/are rejected.
7) ☒ Claim(s) 32-34 and 39-43 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 20 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/2/06, 2/23/07, 9/24/07
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 1-20 and 44-93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 November 2007.
2. Claims 3-20, 44-73, 76-93 and 116-149 are cancelled; claims 1-2 and 74-75 are withdrawn; claims 21-43 and 94-115 are pending.

Information Disclosure Statement

3. Applicant should note that the large number of references in the attached IDS, dated 02 November 2006, have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 21-22, 24, 26-28, 30-31 and 94-115 are rejected under 35

U.S.C. 102(b) as being anticipated by Rocca et al ("Role of the Vagus Nerve in Mediating Proximal Nutrient-Induced Glucagon-Like Peptide-1 Secretion," *Endocrinology*, 140(4), pages 1687-1694. 1999). Regarding claims 21-22, 24, 30-31, 94-95, 97 and 102-103, Rocca discloses (page 1688, "Materials and Methods: Vagal Stimulation") "the celiac branch of the subdiaphragmatic vagus nerve was transected 30 min before the commencement of the experimental procedure. During this interval the distal portion of the celiac branch was placed over a bipolar stimulating electrode connected to a Grass stimulator. This preparation was then immersed in paraffin oil throughout the experiment. The electrical stimulation was begun at 0 min and lasted for 15 min at a voltage of 10 V and a frequency of 20 Hz." The examiner considers this to be applying an electrical signal to a site of the subject which is the distal small intestine of the stomach. Rocca further discloses (page 1692, "Discussion") a "neuroendocrine loop exists that acts to stimulate the ileal L Cells when nutrients are present in the proximal duodenum. The neural component of this proximal-distal loop has been demonstrated to involve the vagus nerve." The vagus nerve "was examined for global effects on basal GLP-1 secretion. This nerve represents the major parasympathetic innervation of the proximal portion of the gastrointestinal tract and is known to influence the secretion of other gut-derived hormones, including GRP and secretin. Left cervical vagotomy significantly depressed the

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basal secretion of gGLI (gut glucagon-like immunoreactivity) to approximately 56% of basal levels in control rats. This finding demonstrates a tonic stimulatory role for the left cervical vagus nerve in regulating secretion of GLP-1 from the L cell." The examiner considers this to be configuring the signal to stimulate cells of the subject to increase the secretion of GLP-1 in order to treat the subject.

6. Regarding claims 26 and 98, Rocca discloses, (page 1694) "As knowledge is gained concerning the functioning of the neuroendocrine loop, examination of this axis can be made in disease states, such as type II diabetes mellitus.

7. Regarding claims 27-28 and 99-100, the examiner considers Rocca's system not to involve applying the signal responsively to detecting eating by the subject. Rocca's system applies the signal periodically ($f = 20$ Hz, as seen above).

8. Regarding claim 96, it is noted that the functional language and introductory statement of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Rocca utilizes the at least one electrode and control unit as claimed by the applicant, Rocca's system is therefore capable of being used in the colon. In addition nothing prevents Rocca's device from being implanted and used in the colon. Therefore, it is capable of use in the colon.

9. Regarding claims 101 and 104-111, the functional language and introductory statement of intended use have been carefully considered but are not considered to impart any further structural limitations over the prior art. Since

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Rocca utilizes a control unit as claimed by the applicant, Rocca's control unit is therefore capable of being used in the claimed manner (e.g., varying at least one parameter of the signal in real time). In addition nothing prevents Rocca's control unit from being used in this manner. Therefore, it is capable of performing the functions claimed.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 23, 25 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rocca et al ("Role of the Vagus Nerve in Mediating Proximal Nutrient-Induced Glucagon-Like Peptide-1 Secretion," *Endocrinology*, 140(4), pages 1687-1694. 1999). Rocca discloses the claimed invention but does not disclose expressly the application of a signal to the colon. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the application of a signal to the small intestine as taught by Rocca, with the signal application in the colon, because the applicant has not disclosed the colon as a stimulation site provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the small intestine

stimulation as taught by Rocca, because Rocca's stimulation of the small intestine results in an increased secretion of GLP-1 as claimed. Therefore, it would have been an obvious matter of design choice to modify Rocca's method to obtain the invention as specified in the claim.

12. Regarding claim 25, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Rocca's type II diabetes mellitus application with application to treat obesity, since it has been held that applying a known technique to a known device ready for improvement will yield predictable results. In this case, stimulating the production of GLP-1 is a known technique for treating obesity, and applying this technique to Rocca's system would yield the predictable result of treating a patient suffering from obesity.

13. Regarding claims 35-38, Rocca discloses the claimed invention but does not disclose expressly the use of pulse bursts. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the constant frequency signal as taught by Rocca, with the bursts of pulses, because the applicant has not disclosed the use of bursts of pulses provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the constant frequency of stimulation signal as taught by Rocca, because Rocca's stimulation signal is able to trigger the release of GLP-1. Therefore, it would have been an obvious matter of design choice to modify the method of Rocca to obtain the invention as specified in the claims. It is further noted, with regards to claims 36-38, that it would have been

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obvious to one having ordinary skill in the art at the time the invention was made to provide a duration between bursts and a frequency of the pulses within each burst within the claimed ranges, since it has been held that discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Allowable Subject Matter

14. Claims 32-34 and 39-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH MALAMUD whose telephone number is (571)272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/
Examiner, Art Unit 3766